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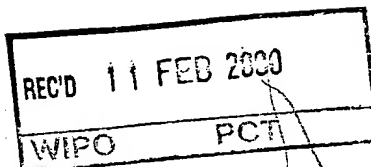


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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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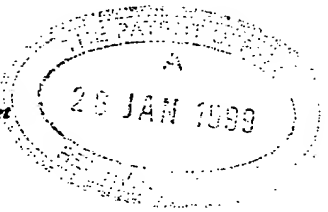
Dated

1st February 2000

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)



The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

41857

2. Patent application number

(The Patent Office will fill in this part)

9901711.3 ✓

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

VC2 Ltd.,

Flat 10 Dacres Lodge,
51 Dacres Road,
Forest Hill,
London, SE23 2NS.
United Kingdom

7576234001

4. Title of the invention

Device for protecting and treating "wounds".

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

FS1177
24-1-2000
TW

James B. King

Kings Patent Agency Limited,
73 Farringdon Road,
London, EC1M 3JQ,

Gill Jennings + Every
Braddgate House
7 Eldon Street
LONDON EC2M 7LH.

1008001

Patents ADP number (if you know it)

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Yes

Patents Form 1/77

9. Enter the number of sheets of any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description

6

Claim(s)

Abstract

Drawing(s)

2

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents (*please specify*)

1

11. Kings Patent Agency Limited
73 Farringdon Road,
London, EC1M 3JB (Agents)

I/We request the grant of a patent on the basis of this application.

Signature

Date

12. Name and daytime telephone number of person to contact in the United Kingdom

Voice: 0171 248 6161 Fax: 0171 831 0926

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TITLE:**Device for protecting and treating "wounds".**

5 This invention relates to a device for the protection and treatment of "wounds" on the body human and is primarily concerned with a device for protecting open "wounds", such as ulcers, burns or gangrenous tissue, for example on the lower limbs, the feet, the hands or lower forearm.

 Of the order of 0.5 to 1% of the population suffers with venous ulceration
10 affecting the lower limbs. On average the length of time an ulcer remains is greater than two years and often ulcers remain unhealed for many years.

 Treatment costs are thus high and ongoing, with "wounds" requiring cleaning and dressing from twice daily to twice weekly using costly lotions and dressings which rarely prove to have useful efficacy. The treatment is therefore
15 very labour intensive, especially to the district nursing service.

 An object of this invention is to provide a device which facilitates the protection and healing of "wounds" by providing an appropriate known beneficial environment around the area of the "wound" and offering cleanliness as well as containing any odours. This invention also provides a method for the
20 treatment of "wounds" using such a device.

 According to this invention there is provided a device for the purpose of facilitating healing of open "wounds", the device comprising an enclosure of a plastics material resistant to the passage of odorous gases, the enclosure having an opening at an end thereof with fastening means to enable the
25 opening to be closed around a limb with an affected part contained within the

enclosure, the opposed end of the enclosure having an internal lining of a fluid absorbent material, an extra fluid absorbent pad positioned within and attached to the enclosure, and an active filter with the means to vent gases through the wall of the enclosure and to reduce odours.

5 In a preferred embodiment the plastics material of the enclosure comprises a multi-layered construction with an intermediate layer of PVDC or EVOH provided to resist the passage of gases. The plastics material may include a layer which is absorbent to odours this being a most preferred feature. Such materials are used in the food packaging industry. The outer layers will
10 conveniently be of an EVA or LDPE material this allowing the enclosure to be formed from two sheets which are welded around the peripheral edges. The plastics material of the enclosure may be of a three, five or seven layer construction as example.

The absorbent lining material may be paper based and held by transverse
15 weld lines. The opening in the enclosure may include an internal absorbent lining forming a "cuff".

The fluid absorbent pad may be of a kind known for their super-absorbency. The active filter may comprise a charcoal material and preferably incorporates a valve means to relieve internal pressures causing ballooning of the enclosure.

20 The enclosure may also include a connector through which oxygen or other gases may be introduced into the enclosure.

For use on the foot the outer part of the enclosure opposite to the open end may have a reinforced part; more specifically an external non-slip layer may be provided.

25 According to this invention there is also provided a method for treating open

"wounds" on the limb of a body, in which method the "wound" is first simply cleaned and the relevant limb enclosed within the device as aforesaid in a substantially air-tight manner.

According to this invention a device is provided which is able to provide a warm and moist environment with adequate oxygenation, whilst maintaining the "wound" clean with no gross contamination occurring. The device is capable also of containing any odours as well as being tolerated by the patient who can be kept mobile whilst wearing the device and avoiding aggravation of the condition.

Further and preferred features of this invention will now be described in more detail and with reference to the drawings showing embodiments by way of examples. In the drawings:

♦ Fig. 1 shows a "wound" protecting "boot" in flat form and in side elevation,

♦ Fig. 2 shows the "boot" of Fig. 1 in section on A-A,

♦ Fig. 3 shows a "wound" protecting "glove" in flat form and in side elevation, and

♦ Fig. 4 shows the "glove" of Fig. 3 in section on A-A.

20

Referring firstly to Figs. 1 and 2 there is shown a "boot" device for the protection and treatment of open "wounds" and particularly, for the protection and treatment of venous ulcerative disease of the lower limbs or burns as examples. The "boot" may be supplied in several sized versions, three being practical, and is formed from two sheets of plastics material A and B, one

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superposed on the other, and joined together by means of heat sealing along edges C. The edges of the sheets are not sealed at the top end D which thus forms an opening for entry of the selected limb into the "boot". In one construction, a single sheet is used with the side opposed to the end D folded over rather than being welded. The fold could, of course, be along another side.

The sheets each comprise a film referred to as a barrier film which is used in the food packaging industry and in for ostomy applications. Such films are generally multi-layered with a middle barrier layer being of either a PVDC or a EVOH material. The outer layers may be typically EVA or LDPE in order that a bond may be formed at the edges to form a pouch. In typical cases the film may be a three, five or seven layered construction depending upon performance required.

The sheets will be transparent to allow the relevant area to be visually inspected.

The inner surfaces of the sheets A and B at the open end D include an absorbent paper layer E extending from the line E1 to the end D and secured by line welds E2 and E3. The end D may be fastened by pulling snugly around the limb and securing by means of a tab D2. This tab may have a peel-off paper layer covering an adhesive which can be pressed onto the outer surface of the "boot" thus providing a snug fit around the limb.

The lower end of the "boot" has a similar lining F of paper material on the inside surfaces and extending between a securing weld F1 and the edge weld C with an intermediate weld connection F2.

The inside surface of the "boot" includes a pad of a super absorbent

material G retained by an overlaid porous paper membrane H and secured by a peripheral weld J. A small aperture K in the side is closed internally by a charcoal filter pad L which prevents the "boot" from ballooning and controls odour.

5 A further aperture in M in the side is closed by a rubber diaphragm N acting as a valve which permits oxygenation if required and by a suitable connection.

A reinforcing strip of plastics material P may be provided adjacent the top D which may include identifying markings.

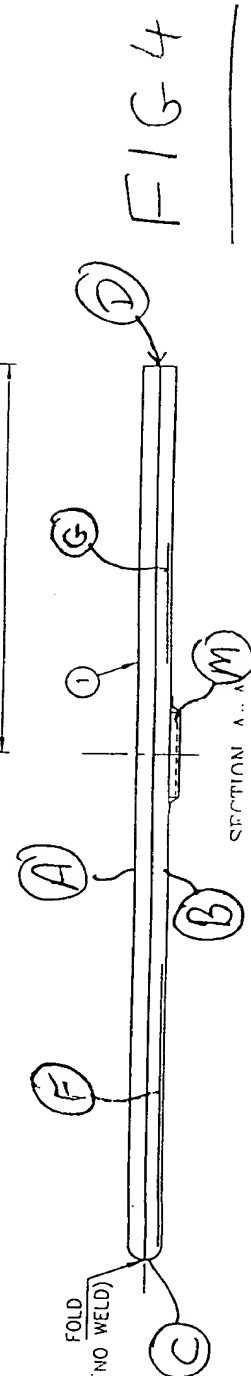
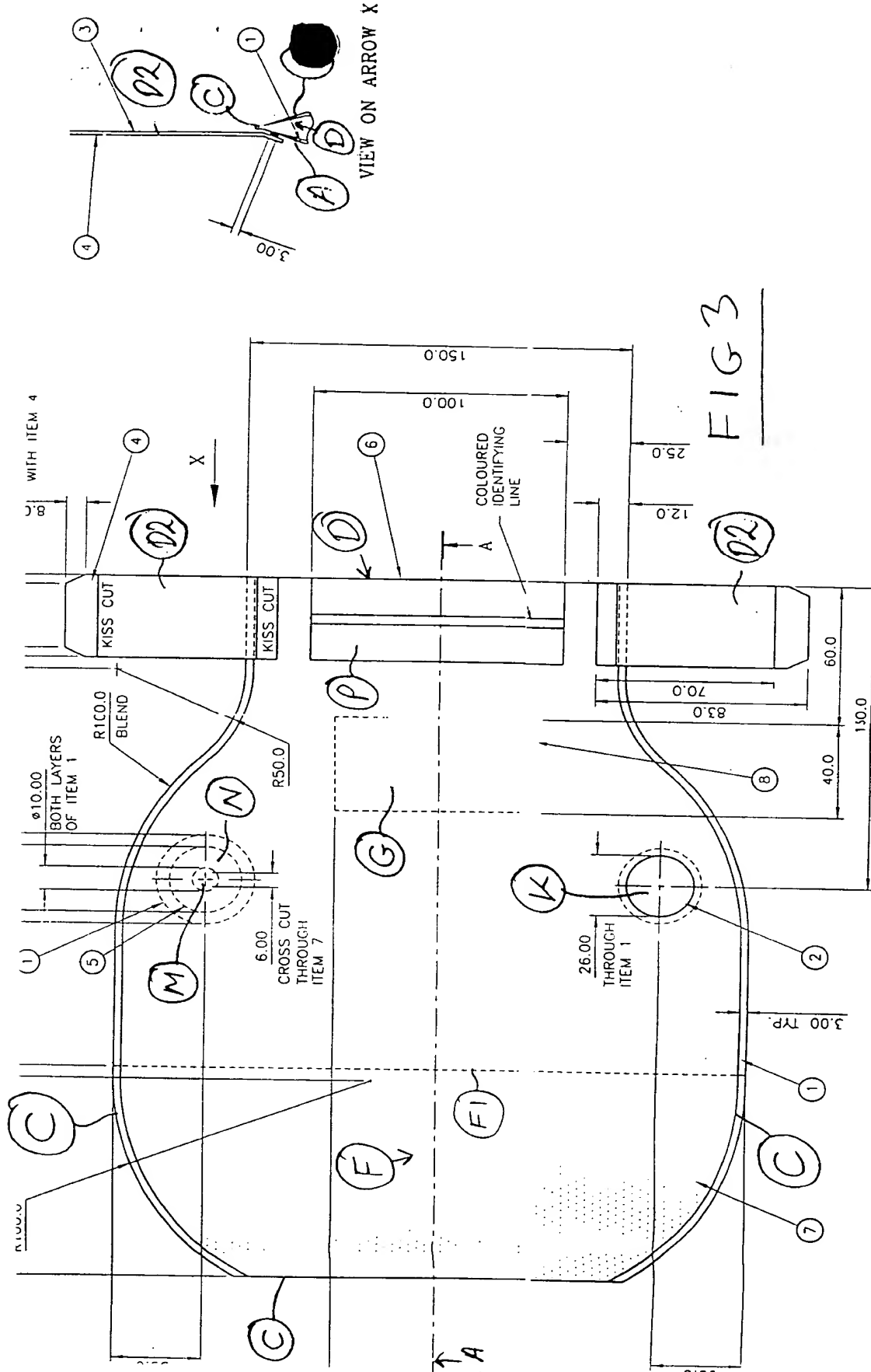
In use, the "boot" will normally be changed on a daily basis and the "wound" area cleaned using simple solutions. The "boot" is then applied and secured by the adhesive tab D2 around for example the leg. The transparent plastic allows the "wound" to be inspected. The plastic provides a warm environment and retains moisture thus promoting healing with excessive moisture being absorbed by the pad material F in the foot part of the "boot" and by the material E in the upper part. Oxygenation may be enhanced by feed through the diaphragm N. Odour is controlled by the charcoal filter L which also permits the interior to "breathe" as well as by the inherent odour absorbing properties of the middle laminate layer of the plastics material.

The construction permits the patient to be freely ambulatory and the outer surface at the foot may include a non-slip coating or layer (not shown).

Figs. 3 and 4 of the drawings show a construction of "glove" embodying the principles of this invention but being used for "wounds" on the hands. The same identifying reference letters are used here to designate parts having the same function as those described in conjunction with Figs 1 and 2.

25 The "glove" will usually be used for burns and may incorporate a pre-

packed pouch of Flamazine, or other agent, attached to the inside of the "glove". In an alternative, there is included a capsule which is broken to release a suitable agent. The "glove" device would be supplied in a sterile pack for use in burns units or as a field dressing primarily for military use. Apart from shape and configuration differences the "glove" uses the same materials and construction as the "boot".



PCT/GE 00/00208

23rd Feb 26-1-2000

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